HFI 35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445

Telephone (714) 798-7600

D1455B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

March 3, 1998 WL-19-8

Jack Brown
President
Gish Biomedical Inc.
2681 Kelvin Avenue
Irvine, CA 92614

Dear Mr. Brown:

During an inspection of your firm conducted between October 31 to December 17, 1997, our investigators determined that your firm manufactures infusion pumps. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your EZ Flow Model 480 Ambulatory/Pole Mounted Infusion pump and the EZ Flow Model 480 Multi-Therapy Infusion pump devices are adulterated under Section 501(f)(1)(B) of the Act in that they are a class III device under Section 513(f) and do not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a) or approved application for investigational device exemption under Section 520(g).

The EZ Flow Model 480 Ambulatory/Pole Mounted Infusion pump and the EZ Flow Model 480 Multi-Therapy Infusion pump are misbranded under Section 502(o) in that a notice, or other information, was not provided to FDA as required by 21 CFR 807.81(a)(3)(i), such that major modifications or changes in design were made that could significantly affect the safety and effectiveness of the devices. Such changes included a change of energy (AC vs. 9 VDC), conditions of use, syringe vs. reusable cassettes, dosages and range, operating principle (analog vs. microprocessor controls), new communication capabilities and changes in the intended use which constitute significant changes or modifications that require a premarket notification as required by 21 CFR 807.81(a)(3)(ii).

We acknowledge your written response of January 9, 1998 advising our office that you terminated all further marketing and sales of the existing EZ Flow 480 infusion pump and that the pumps in the field will have their PCA mode of administration removed. Regardless, the original design was cleared for the administration of analgesics only by small volume syringe infusion and not with its current configuration of deliveries and dosages.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to assure that each of the noted violations has been corrected.

Your response should also include an explanation of the specific steps taken to prevent the recurrence of similar violations. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,

Tom Allesi/for

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn.: Chief, Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320